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EXAMINER	
SELLMAN, CACHET I	

ART UNIT	PAPER NUMBER
1762	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/782,412	GRIGNANI ET AL.	
	Examiner	Art Unit	
	Cachet I. Sellman	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made of the amendment filed by the applicant on5/17/2007, in which claims 1-42 were cancelled and claims 43-70 were added. Claims 43-70 are currently pending in U.S. Application Serial No. 10/782,412.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 43, 69 and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by RD 434009A.

'009 discloses a process for coating a stent with a therapeutic agent where the therapeutic agent is provided as a paste on a carrier as a mat then the stent is rolled (pressure applied) over the paste covered carrier to coat the stent. The process is performed without any electrostatic charge as required by **claims 43, 69 and 70.**

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 43, 61-65 and 67-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Verlee et al. (US 2004/0202773) in view of RD 434009A.

Verlee et al. discloses a process for applying a beneficial agent (beneficial agent includes active agents, polymers and solvents used either alone or in combination) in ether a paste or powder form [abstract, 0012,0071 and 0058] to a selected portion of a stent surface [0053]. Verlee et al. teaches applying the coating using a fluid jet application. The stents made using the process can be sued in blood vessels. Verlee et al. does not disclose providing a bed of paste or powder then applying a pressure in order to coat the stent with the active ingredient as required by **claim 43**.

However, '009 discloses a process for coating stents used in blood vessels with a active agent (therapeutic agent) by soaking a carrier material with the active agent in paste form then rolling the stent over the carrier (applying pressure) to coat the stent with the active agent. '009 teaches that this process is advantageous because it does not require the complexity of preloaded therapeutic agent delivery devices which allows cardiologist the freedom to choose the most suitable active agent.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the process taught by Verlee et al. to include rolling the stent to coat as taught by '009 because both are directed towards coating stents used in blood vessels and '009 further states that the process is advantageous because it does not require the complexity of preloaded therapeutic agent delivery devices which allows cardiologist the freedom to choose the most suitable active agent.

Verlee et al. ('773) teach (page 5, [0055]) the stent can be in an expanded or unexpanded, i.e. contracted, state during the loading of active substances. The underlying structure of the stent can be virtually any structural design. Verlee et al. ('773) are silent concerning that the structure design of the stent is radially expanded or radially contracted; however, Verlee et al. ('773) teach the stents are expandable (page 1, [0007] and also the design of stents shown on Fig. 6, 7, and 9 of Verlee et al. ('773) are inherently radially expanded. Drug eluted stents usually are delivered to the coronary vasculature in their contracted state until a balloon portion thereon is positioned across an occlusive lesion. Once in position, the balloon is inflated to radially expand stent against the vessel wall. Therefore, after a radially expanded stent is loaded with active substance, it is then inherently subject to radial contraction as required by **claims 61 and 62**.

Verlee et al. ('773) teach (page 5, [0055]) the surface of the prosthesis, i.e. stent can include one or more reservoirs or cavities formed therein. Verlee et al. ('773) further teach (page 13, [0121]) a polymer overcoat can be applied over the beneficial agent, i.e. active substance. Such a deposition configuration with cavities is particularly

beneficial for minimizing delamination of the active substance as required by **claims 63 and 68**.

Verlee et al. ('773) teach the active substance is (page 5, [0061]) tacrolimus, i.e. FK 506. The stent (page 5, [0058]) is at least partially loaded with a drug, i.e. FK509 or composition of matter comprising drug, thus meeting the limitation of **claims 64-65**.

In regards to **claim 67**, Verlee et al. ('773) teach the active substance is (page 5, [0061]) tacrolimus, i.e. FK 506. Additionally, the agents or drug formulations can have various known forms such as solutions, dispersions, pastes and particles. Verlee et al. ('773) further teach the active substance (page 7, [0076]) can be mixed with a suitable binder or polymer to for a coating mixture, which is prepared in higher or lower concentrations of active substance as desired. Verlee et al. ('773) fail to specifically teach the viscosity of the paste of FK506 for the coating process. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the viscosity of the paste with a base of FK506 to the range of 1000,000 to 120,000 cps, in order to provide an effective coating. Since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering an optimum or workable ranges involves only routine skill in the art. (See M.P.E.P.2144.05 IIA)

6. Claims 43, 58-59, 64 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weber et al. (US 6743463) in view of RD 434009A.

Weber et al. discloses a method for selectively spray coating a stent (col. 5, lines 37-40) with a formulation consisting of polymers and biological materials in the form of powder (col. 9, lines 24-27 and col. 10, lines 53-54).

Weber et al. does not teach coating the stent using pressure and without electrostatic charge as required by **claim 43**.

However, '009 discloses a process for coating stents used in blood vessels with a active agent (therapeutic agent) by soaking a carrier material with the active agent in paste form or in suspension (particles (powder) in a fluid) then rolling the stent over the carrier (applying pressure) to coat the stent with the active agent. '009 teaches that this process is advantageous because it does not require the complexity of preloaded therapeutic agent delivery devices which allows cardiologist the freedom to choose the most suitable active agent.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the process taught by Weber et al. to include rolling the stent to coat as taught by '009 because both are directed towards coating stents used in blood vessels and '009 further states that the process is advantageous because it does not require the complexity of preloaded therapeutic agent delivery devices which allows cardiologist the freedom to choose the most suitable active agent.

Weber et al. ('463) teach that the active substance comprises immunosuppressant such as tacrolimus, i.e. FK509 (col. 12, line 1-2). The powder used in the coating comprised of particles having an average diameter from about 0.5 micron to about 250 micron (col. 10, line 36-37) as required by **claims 64 and 66**.

Weber et al. ('463) teach after the powder coating process, the stent is subjected to a heat treatment, for example using IR heating (col.10, lone 41-42) as required by **claims 58-59**.

7. Claims 44, 48 and 50-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weber et al. in view of '009 as applied to claim 43 above and in further view of Nacker et al. (US 5925402).

The teachings of Weber et al. in view of '009 as applied to claim 43 are as stated above.

Weber et al. ('463) in view of '009 fail to teach removing the active agent from the other area of the surface of said stent as required by **claim 44**.

Nacker ('402) teaches a method of patterned coating on a substrate. The patterned images are produced by depositing a layer of coating powder on a substrate, directing a laser beam at the selected area of the coating layer so as to fuse an image on the selective area, and subsequently removing non-fused coating powder from remaining area of the coating layer (col. 1, line 21-27). The non-fused coating powder can be removed by compressed air (col.3, line 10), i.e. jets of fluid (**claims 50-51**).

Since Weber et al combined with '009 teach a method of coating stent on selected area and Nacker ('402) teaches a method to remove the coating on the undesired area with jets of fluid, Nacker ('402) would have reasonably suggested to improve the coating by clean up undesired coating material. Therefore, it would have been obvious to one of ordinary skill in the art to modify the method of Weber et al. in combination with '009 using the teaching of Nacker ('402) with the expectation of

successful results of providing the stent with active agent in a geometric pattern for the purpose of delivery of drug into the body in a precise manner. In regard to the requirement of removing active substance with jets of water or jets of N2, it is the Examiner's position that one of ordinary skill in the art would recognize the functional interchangeability of jets of air with jets of N2 as stated in **claims 54-55**, and jets of water as stated in **claims 52-53**.

Weber et al. ('463) teach after the powder coating process, the stent is subjected to a heat treatment, for example using IR heating (col.10, line 41-42) as required by **claims 58 and 60**.

8. Claims 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhong et al. (US 6676987) in view of RD 434009 A.

Zhong et al. teaches a process for depositing a powder of active agents (col. 5, lines 55-56) on selected areas and other areas of a surface of a stent (col. 2, line 45 and Fig. 2) by using a bubble jet printing head system (abstract).

Zhong et al. does not teach using a bed or mat of active agent then coating the stent by applying a pressure thereto as required by **claim 43**.

However, '009 discloses a process for coating stents used in blood vessels with a active agent (therapeutic agent) by soaking a carrier material with the active agent in paste form then rolling the stent over the carrier (applying pressure) to coat the stent with the active agent. '009 teaches that this process is advantageous because it does not require the complexity of preloaded therapeutic agent delivery devices which allows cardiologist the freedom to choose the most suitable active agent.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the process taught by Zhong et al. to include rolling the stent to coat as taught by '009 because both are directed towards coating stents used in blood vessels and '009 further states that the process is advantageous because it does not require the complexity of preloaded therapeutic agent delivery devices which allows cardiologist the freedom to choose the most suitable active agent.

Zhong et al. further teaches applying a masking material on selected areas of the stent and etching the stent surface area that is not covered by the masking material to remove coating on the other areas, as required by **claim 44**.

9. Claims 50-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhong et al. ('987) in view of '009 as applied to claim 43 above in further view of Zhong et al. (US 6156373).

The teachings of Zhong et al. ('987) in view of '009 as applied to claims 43-44 are as stated above.

Zhong et al. ('987) does not teach removing the active substance by fitting the stent on a nozzle emitting jets of fluid from the nozzle inside the stent as required by claim 49.

However, Zhong et al. ('373) teach a method of coating stent (col. 11, line 20-29) and removing the excess coating on the stent by inserting the stent on a tool i.e. nozzle (see fig. 6 and 7) comprising a perforatd tube and emitting gas streams, i.e. jets of fluid from the nozzle and through the inside of the stent.

Both processes concerning remove undesired coating on the stent surface. Zhong et al. ('373) would have reasonably suggested the use of nozzle emitting jets of fluid inside of the stent. It would have been obvious to one having ordinary skill in the art to utilize the nozzle of Zhong et al. ('373) in place of the etching process taught by Zhong ('987), in order to effectively remove the coating on the inner surface of the stent.

In regards to **claims 50-55**, it is the Examiner's position that one of ordinary skill in the art would recognize the functional interchangeability of jets of air with jets of N2 and jets of water.

Zhong et al. ('987) teach a process for precisely depositing the powder of active agents on the selected area and the other area of the surface of a stent, and removing the undesired coating on the other area by etching. Zhong et al. ('987) fail to teach removing the active substance by rubbing the surface of the stent with a support, which has a compliant surface as required by **claims 56-57**. It would have been obvious to one having ordinary skill in the art to remove the undesired coating on the other region by utilizing a functional equivalent rubbing support to clean up the coating pattern on the stent.

10. Claims 43, 45, 47 and 58-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwarz et al. (US 6368658) in view of RD 434009A.

Schwarz et al. ('658) teach a process for coating stent (col. 3, line 48) by depositing a formulation, which consists of polymers and biological active materials (col.2, line 10) in the form of particles, i.e., powder (col. 2, line12) on selected surface regions of stent (col. 2, line 6-7).

Schwarz et al. ('658) teach that stent may be loaded into a conventional fluidized bed chamber (col.9, line 41-45), in which air is introduced into a bed of the medical device from below while the coating material is sprayed onto the fluidized devices from above. Schwarz et al. ('658) further teach that partial coating is accomplished (col. 11, line 56-58), for example, using known masking or similar techniques to result in the coating of predetermined stent segments.

Schwarz et al. fails to teach applying the coating to the stent by applying pressure as required by **claim 43**.

However, '009 discloses a process for coating stents used in blood vessels with a active agent (therapeutic agent) by soaking a carrier material with the active agent in paste form then rolling the stent over the carrier (applying pressure) to coat the stent with the active agent. '009 teaches that this process is advantageous because it does not require the complexity of preloaded therapeutic agent delivery devices which allows cardiologist the freedom to choose the most suitable active agent.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the process taught by Schwarz et al. to include rolling the stent to coat as taught by '009 because both are directed towards coating stents used in blood vessels and '009 further states that the process is advantageous because it does not require the complexity of preloaded therapeutic agent delivery devices which allows cardiologist the freedom to choose the most suitable active agent.

As stated above Schwarz et al. teaches the use of a mask to selectively coat the stent as required by **claims 45 and 47**.

In regards to claim 46, Schwarz et al ('658) teaches a process for coating stent by depositing a formulation which consists of polymers and biological active materials in the form of powder on entire surface of stent and utilize a mask to coat desired area. Schwarz et el ('658) do not teach removing the undesired powder coating on certain area with two sets of mask. It would have been obvious to one having ordinary skill in the art at the time invention was made duplicating a process with a different mask for different region/design, since it has been held that duplication of the essential working parts of a device involves only routine skill in the art would not involve a patentable step. See M.P.E.P 2144.04 VI B.

Schwarz et al. ('658) further teach polymerization or treatment (col.11, line 46-52) of the stent surface using microwave, ultraviolet light, and thermal evaporation technique. Additionally, a protective layer can be applied as a top coating (col. 6, line 17-18) as required by **claims 58-59**.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cachet I. Sellman whose telephone number is 571-272-0691. The examiner can normally be reached on Monday through Friday, 7:00 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cachet I Sellman

Examiner
Art Unit 1762

cis

/William Phillip Fletcher III/
Primary Examiner

August 1, 2007